means the cefmenoxime activity (potency) contained in 1.0482 micrograms of the cefmenoxime master standard.

(95) *Cefixime.* The term ''microgram'' applied to cefixime means the cefixime activity (potency) contained in 1.126 micrograms of the cefixime master standard.

(96) *Cefotiam.* The term ''microgram'' applied to cefotiam means the cefotiam (potency) contained in 1.144 micrograms of the cefotiam master standard.

(97) *Clindamycin phosphate.* The term ''microgram'' applied to clindamycin phosphate means the clindamycin phosphate (potency) contained in 1.252 micrograms of the clindamycin phosphate master standard.

(98) *Mupirocin.* The term ''microgram'' applied to mupirocin means the activity (potency) calculated as mupirocin activity (potency) contained in 1.075 micrograms of the mupirocin master standard.

(99) *Cefmetazole.* The term ''microgram'' applied to cefmetazole means the cefmetazole (potency) contained in 1.002 micrograms of the cefmetazole master standard.

(100) *Cefpiramide.* The term ''microgram'' applied to cefpiramide means the cefpiramide (potency) contained in 0.994 microgram of the cefpiramide master standard.

(101) *Clarithromycin.* The term ''microgram'' applied to clarithromycin means the clarithromycin (potency) contained in 1.010 micrograms of the clarithromycin master standard.

(102) *Azithromycin.* The term ''microgram'' applied to azithromycin means the azithromycin (potency) contained in 1.063 micrograms of the azithromycin master standard.

(103) *Cefprozil.* The term ''microgram'' applied to cefprozil (Z) means the cefprozil (Z) potency contained in 1.060 micrograms of the cefprozil (Z) master standard. The term ''microgram'' applied to cefprozil (E) means the cefprozil (E) potency contained in 1.106 micrograms of the cefprozil (E) master standard.

(104) *Idarubicin.* The term ''microgram'' applied to idarubicin means the idarubicin activity (potency) calculated as idarubicin hydrochloride contained in 1.036 micrograms of the idarubicin master standard.

(105) *Loracarbef.* The term ''microgram'' applied to loracarbef means the loracarbef (potency) contained in 1.059 micrograms of the loracarbef master standard.

(106) *Rifabutin.* The term ''microgram'' applied to rifabutin means the rifabutin (potency) contained in 1.022 micrograms of the rifabutin master standard.

(107) *Cefpodoxime proxetil.* The term ''microgram'' applied to cefpodoxime proxetil means the cefpodoxime (potency) contained in 1.304 micrograms of the cefpodoxime proxetil master standard when dried.

[39 FR 18925, May 30, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 430.6, see the List of CFR Sections Affected appearing in the Finding Aids section of this volume.

Subpart B—Antibiotic Drugs Affected by the Drug Amendments of 1962

§ 430.10 Certification or release of antibiotic drugs affected by the drug amendments of 1962.

(a) Before the 1962 amendments to it, the Federal Food, Drug, and Cosmetic Act only permitted the Food and Drug Administration to provide for the certification of batches of antibiotic drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative of them. FDA certified those drugs under regulations promulgated on the basis of scientific proof of the drugs' safety and effectiveness. Most drugs containing an antibiotic other than one of those listed were subject to the new drug provisions of the act, which required that an applicant show that the drug was safe and obtain FDA approval of a new drug application before marketing it. An affirmative showing of effectiveness was not then required to obtain approval. Some antibiotic drugs that were not subject to certification, however, were also not subject to the new drug provisions of the act under informal FDA opinions that the drug was ''not a new drug'' or ''no longer a new drug.'' FDA

revoked those opinions under § 310.100 of this chapter.

(b) The 1962 amendments amended section 507 of the act to require the certification, release without certification, or exemption from certification, of all antibiotic drugs on the basis of scientific proof of safety and effectiveness. The amendments provided that FDA implement them for antibiotic drugs that were marketed on April 30, 1963 and were not subject to the certification provisions on that date. FDA is implementing the amendments with respect to antibiotic drugs formerly subject to the new drug provisions of the act through its Drug Efficacy Study Implementation (DESI) program under which the agency is evaluating those antibiotic drugs for efficacy. Until FDA completes that evaluation it will permit continued marketing of those antibiotic drugs under paragraph (c) of this section. The agency is also implementing the 1962 amendments with respect to antibiotic drugs formerly not subject to either the certification or new drug provisions of the act and the agency is evaluating those antibiotic drugs for both safety and efficacy. Until FDA completes that evaluation, it will permit continued marketing of those antibiotic drugs under paragraph (d) of this section.

(c) Unless exempted from certification, FDA will certify or release antibiotic drugs which on April 30, 1963 were the subject of an approved new drug application under section 505 of the act, under regulations providing for certification of the drugs. Although the initial regulation for each of these drugs established under section 507(h) of the act was not conditioned upon an affirmative finding of the effectiveness of the drug, FDA is proceeding under its DESI program to amend or repeal those regulations to provide for certification of those drugs only if they had been shown to be both safe and effective.

(d) Unless exempted from certification, FDA will release without certification an antibiotic drug that was marketed on April 30, 1963, but not subject to certification, and not subject to an approved new drug application on that date, unless FDA has made a determination that the drug has not been shown to be safe or lacks substantial evidence of effectiveness under the DESI program. FDA is proceeding under its DESI program to establish regulations under section 507 to provide for certification of those drugs only if they have been shown to be safe and effective.

[50 FR 7516, Feb. 22, 1985]

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

Subpart A—General Provisions

Subpart B—Administrative Procedures

Subpart C—Records and Reports

Subpart D—Confidentiality of Information

AUTHORITY: 21 U.S.C. 351, 352, 353, 355, 357, 379e; 42 U.S.C. 216, 241, 262; 5 U.S.C. 552.

SOURCE: 39 FR 18934, May 30, 1974, unless otherwise noted.

Subpart A—General Provisions

§ 431.1 Requests for certification, check tests and assays, and working standards; information and samples required.

(a) A request for certification of a batch (antibiotic Form 7/Form FDA–1677) is to be addressed to the Food and